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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: (510) 337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-39799

May 21, 1997

John D. Lemstra
Walt Lemstra Dairy
24643 Road 36
Tulare, California 93274

WARNING LETTER

Dear Mr. Lemstra:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on May 5 and 6, 1997, by Food and Drug Administration (FDA) Investigator Christopher J. Lee have revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) as follows:

A food is adulterated under Section 402(a)(2)(D) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On January 14, 1997, you consigned a dairy cow (identified by USDA laboratory report number 260746) for slaughter as human food. This cow was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal antibiotic drug residues. USDA analysis of tissues from this animal revealed the presence of

sulfadimethoxine in the liver at 4.70 parts per million (ppm) and in the muscle at 2.50 ppm. The tolerance level for sulfadimethoxine in the edible tissues of cattle has been established at 0.10 ppm.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate record keeping system for determining the medication status of animals you offer for slaughter.

2. You lack an adequate system for assuring that animals to which you administer have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

3. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.

The Albon brand of sulfadimethoxine that your use to treat your cows is adulterated under Section 501(a)(5) of the Act, in that it is a new animal drug within the meaning of Section 201(v) and is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with its approved labeling. Labeling for Albon prescribes two boluses followed by one bolus per day for three to four days. Labeling also requires a seven day withdrawal period prior to slaughter for food use. Failure to adhere to the prescribed dosage and withdrawal time is likely the cause of the presence of violative levels of sulfadimethoxine in the tissues of the animals you sold for food use.

You are using the drug Oxyject 100 brand oxytetracycline hydrochloride in a manner not in conformance with its approved labeling. Labeling for oxytetracycline hydrochloride specifies

it is to be administered on non-lactating dairy animals. Your practice of administering it to your lactating dairy animals is an unapproved use for which safety and efficacy have not been established.

Your use of drugs for treating your dairy cows does not conform to approved labeling instructions. Failure tc adhere to the instructions for approved drugs, including withdrawal times and routes of administration presents the possibility that illegal residues will occur and makes the drug unsafe to use.

We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Your firm has established a history of offering animals for sale for human food use which have been found to be adulterated with drug residues. According to USDA analytical reports, during the period of May 25, 1989, through April 2, 1996, your firm sold three other dairy cows which contained violative levels of penicillin and oxytetracycline. An inspection of your dairy was conducted on March 27, 1989. During this inspection, you were warned that it is illegal to market animals containing violative levels of antibiotics in their edible tissues. A Regulatory Letter, dated July 13, 1990, was sent to you as a result of the violations found during that inspection. Also, the USDA sent you a letter for each instance in which their analysis found violative levels of drug residues in your cull dairy cows. You have failed to take adequate corrective action. It is your

responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen (15) days of the receipt of this letter, please notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Christopher J. Lee, Investigator, P.O. Box 169, Fresno, CA 93707.

Sincerely yours,

Patricia C. Ziobro

Patricia C. Ziobro
District Director
San Francisco District

cc: [redacted]